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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,357	10/31/2001	Jerome T. Hartlaub	11738.00045	2290
27581	7590	08/23/2004	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			LAU, TUNG S	
			ART UNIT	PAPER NUMBER
			2863	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/001,357

Applicant(s)

HARTLAUB, JEROME T.

Examiner

Tung S Lau

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 and 19-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 12, 15, 16, 18 and 29-38 is/are rejected.
- 7) ☒ Claim(s) 2, 4-8, 13, 14, 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Election/Restrictions***

1. Claims 9-11, 19, 21-25, 20, 26-28 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected without traverse invention as noted in paper 3-23-2004.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

a. Claims 1, 3, 33, 34, 35, 36, 37, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al. (U.S. Patent 5,188,106) in view of Wojcicki et al. (U.S. Patent 5,190,522).

Regarding claim 1:

Nappholz discloses a computing device in communication with an implantable drug delivery device for delivering at least one drug to a patient, the drug delivery device having a reservoir containing at least one drug and a nonconformance monitor module configured to monitor at least one performance parameter, the computing device comprising in combination: (a) a memory having stored therein pump performance acquisition instructions (Col. 29, Lines 24-67); (b) a telemetry module (fig. 10, unit 103) providing bi-directional communication between the computing device and the implantable drug delivery device and providing the

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pump performance acquisition instructions to the implantable drug delivery device and receiving pump performance data from the implantable drug delivery device (fig. 10, unit 110, 102, 115, 120, Col. 33, Lines 42-56).

Regarding claim 3, Nappholz discloses the memory includes the patient performance requirement information (Col. 33, Lines 42-56).

Regarding claim 33, Nappholz discloses the system is a non-programming (Col. 16, Lines 37-52).

Regarding claim 34, Nappholz discloses no program change (Col. 2, Lines 3-21).

Regarding claim 35, 36 Nappholz discloses programming change (Col. 16-17, Lines 53-14).

Regarding claim 37, Nappholz discloses connect to an external device (fig.10, unit 103, 100).

Regarding claim 38, Nappholz discloses event associate with pump (Col. 2, Lines 3-41).

Nappholz does not disclose a nonconformance management module contained within the memory receiving the pump performance data and determining whether the pump is conforming to performance requirements, and determining what action should be taken if non conformance is determined; Wojcicki discloses a nonconformance management module contained within the memory receiving the pump performance data and determining whether the pump is

conforming to performance requirements, and determining what action should be taken if non conformance is determined (Col. 4, Lines 15-39), in order to have an accurate monitoring system and guarantees that the drug infused into the body of the patient (Col. 4, Lines 3-6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Nappholz to have a nonconformance management module contained within the memory receiving the pump performance data and determining whether the pump is conforming to performance requirements, and determining what action should be taken if non conformance is determined taught by Wojcicki in order to have an accurate monitoring system and guarantees that the drug infused into the body of the patient (Col. 4, Lines 3-6).

**b.** Claims 15, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wojcicki et al. (U.S. Patent 5,190,522) in view of Nappholz et al. (U.S. Patent 5,188,106).

Wojcicki discloses a system including the subject matter discussed above except telemetry module. Nappholz discloses telemetry module in fig. 10, unit 103, in order to determine the system status remotely (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Wojcicki to have telemetry module taught by Nappholz in order to determine the system status remotely (abstract).

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 12, 16, 29, 30, 31, 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Wojcicki et al. (U.S. Patent 5,190,522).

Regarding claim 12:

Wojcicki discloses an implantable drug delivery device having performance data reporting capability comprising in combination: (a) a memory having stored therein pump performance acquisition instructions (Col. 4, Lines 15-39, fig. 1, unit 5, 3) ; (b) at least one nonconformance monitor module for monitoring at least one pump operation variable in accordance with the pump performance acquisition instructions to produce pump performance data (Col. 4, Lines 15-39); and (c) a non-conformance management module receiving the pump performance data, determining whether the pump is conforming to performance

requirements, and determining what action should be taken if non-conformance is determined (Col. 4, Lines 15-39).

Regarding claim 16, Wojcicki discloses the nonconforming module patient requirements information is received by non-conformance module (Col. 2-3, Lines 59-7, Col. 1, Lines 29-49).

Regarding claim 29, Wojcicki discloses the nonconforming module determine data is of a non-program changes (Col. 2-3, Lines 61-7, fig. 1, unit 6, 3, 5).

Regarding claim 30, Wojcicki discloses the nonconforming module determine data perform no programming changes (Col. 2-3, Lines 61-7, fig. 1, unit 6, 3, 5).

Regarding claim 31, Wojcicki discloses the nonconforming module determine whether pump data is indicate of change (Col. 4, Lines 15-39, fig. 1, unit 5, 3).

Regarding claim 32, Wojcicki discloses the nonconforming module perform programming change to system (Col. 2-3, Lines 61-7, fig. 1, unit 6, 3, 5).

### ***Claim Objections***

4. Claims 2, 4, 5-8, 13, 14, 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitation of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance: prior art fail to teach the pump performance data is selected from the group consisting of pump

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reservoir pressure, fluid outlet pressure, propellant pressure, fluid flow rate, battery current drain, motor current drain, motor drive current profile, battery voltage, and physiologic sensor output level; pump manufacturer requirement information; includes a scheduling module for scheduling an appointment to service the device.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Response to Arguments***

5. Applicant's arguments filed 6/22/2004 have been fully considered but they are not persuasive.

A. Applicant argues in the lengthy arguments that the prior art has no reason to combine. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941



(Fed. Cir. 1992). In this case, both Nappholz and Wojcicki in the knowledge generally available to one of ordinary skill in the art in the same area of invention.

**B.** Applicant continues to argue in the lengthy arguments that the prior art does not show the 'memory having stored pump performance acquisition instruction'.

Wojcicki discloses 'memory having stored pump performance acquisition instruction' in Col. 4, Lines 15-42, Col. 2-3, Lines 61-7.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.").

See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

Reminds to the applicants that during patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification." Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969).

While the meaning of claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode

of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allowed. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

When not defined by applicant in the specification, the words of a claim must be given their plain meaning. In other words, they must be read as they would be interpreted by those of ordinary skill in the art. > Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001)

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tung S Lau whose telephone number is 571-272-2274.

The examiner can normally be reached on M-F 9-5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on 571-272-2269. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-5841 for regular communications and 703-308-5841 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0956. TC2800 FAX Telephone Numbers: 703-872-9306

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TL

  
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